

## REMARKS

### I. Status of the Claims

Claims 1-31 were filed with the original application, and claims 2-6 and 21-31 have now been canceled. New claims 32-36 have been added. Claims 1, 7-10, 18-20 and 32-34 are under consideration and stand rejected under 35 U.S.C. §§101, 112 (first and second paragraphs), and 102. The specific grounds for rejection, along with applicant's response thereto, are set out in detail below.

### II. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1, 7-10, 18-20, 32, and 33 stand rejected as allegedly indefinite. Applicant traverses. The individual rejections are addressed below:

**Claim 1** is said to be vague in the use of the terms “four common allotypes” and “antigens.” Applicants traverse, first, “antigens” and described as MHC antigens, which are well known antigenic determinants. Further, it is not clear whether the examiner finds “allotypes” vague, or whether it is “common allotypes” that is objectionable. In any event, allotype is a well known term that describes the antigenic profile of an individual's MHC antigens. “Common” simply refers to those allotypes that are more prevalent in a given species. Thus, it is believed that all of these terms are clear and definite.

The examiner also objects to a composition as having a single element. The claims are directed to *a composition* that comprises at least *four common allotypes* of a given species. As stated above, an allotype is the antigenic profile generated by the MHC

antigens found in a given individual. Thus, one organism can only have one allotype. In order for a composition of matter to have four allotypes, it must contain products from at least four individuals. Thus, the rejection is based on an incorrect factual premise, and is believed to be improper.

**Claim 7** is said to be indefinite in not defining “antigens” or “other alloantigens.” With respect to the latter, the language has been deleted from the claim. With respect to the former, again, the antigens are described as MHC antigens. This is sufficiently definite and descriptive, and thus the rejection is believed to be improper.

**Claim 8** is said to fail to limit the claim from which it depends. This is absolutely false. Claim 1 requires only four allotypes from a given species to be represented. Claim 8 required that *all* allotypes of given species be represented, which is more restrictive, and thus more limiting.

**Claim 10** is said to be not only indefinite, but “incomprehensible” for use of the term “the following human allotypes” without any recitation of such. As can be seen from the previous amendment, claim 10 is described as “original,” yet original claim 10 does list numerous allotypes. Those allotypes have been inserted in the claim, and the claim has been further amended to include a period at its conclusion.

In light of the foregoing, applicant respectfully requests reconsideration and withdrawal of the rejection.

### **III. Rejection Under 35 U.S.C. §101**

According to the examiner, the claims 1 and 7-10 “do not sufficiently distinguish over nucleic acids, proteins, cell as they exist naturally,” and hence run afoul of the “natural products” doctrine of §101. Applicant traverses.

First, no nucleic acids are recited in the claims. Second, the claims are directed to *a composition* that comprises at least *four common allotypes* of a given species. An allotype is the antigenic profile generated by the MHC antigens found in a given individual. Thus, one organism can only have one allotype. In order for a composition of matter to have four allotypes, it thus cannot be a product of nature. Thus, the rejection is based on a incorrect factual premise, and is therefor improper.

Reconsideration and withdrawal of the rejection is therefore respectfully requested.

### **IV. Rejection Under 35 U.S.C. §112, First Paragraph**

Claims 1, 7-10, 18-20, 32 and 33 stand rejected under §112, first paragraph, as lacking an adequate written description of the invention. Thus, the examiner alleges that applicant was not in possession of the invention as now claimed at the time of filing. Applicants traverse.

The examiner’s starts by arguing that “Applicant has only disclosed a general method of generating an anti-major histocompatibility complex (MHC) immune response. However, the disclosure does not provide for a specific product isolated from a mammal in general or human in particular that can be administered to a suitable host.” These statement evince a complete lack of understanding of the invention and of the wealth of information provided in the instant specification.

The present invention derives from the inventors observation that persons immunized with cells from other individuals appear to have an increased ability to fight off viral infections. Enveloped viruses, by definition, will carry allotypes of the individuals in which they were produced. Thus, the inventor determined that the allotypic antigens on the surface of enveloped viruses could be good targets for the host immune system, but only if that immune system was “primed” against those allotypes – something that does not happen naturally.

The proposal to immunize otherwise healthy persons with a plurality (in this case at least four) different allotypes is unique. By using at least four different allotypes, a large segment of the putative population. In contrast to the examiner’s suggestions, various of these allotypes were known at the time of filing. FIGS. 1-3 provide lists of HLA allotypes and their frequency distribution by ethnic group. More significantly, the use of whole cells as vaccines is described in great detail in the specification (see pages 33-38), thereby obviating the need to identify and purify specific antigens. As stated on page 37, “no more than three of four cell lines will be required to provide a vaccine that encompasses 100% of the HLA antigen of the target population.” Thus, applicants submit that the invention is described in more than sufficient detail to lead one of skill in the art to believe that the applicant have possession thereof.

Next, the examiner avails himself of *University of California v. Eli Lilly and Co.* Unfortunately, the facts of that case have absolutely no relevance to the situation here. *Lilly* dealt with claims to a nucleic acid from a species that had not yet be obtained or described structurally by the applicants. In finding a lack of written description, the Federal Circuit summarized previous cases that held that one must know the structure of an isolated DNA molecule in order to claim it. Here, however, gene and protein sequences for many of the antigens at issue were known at the time of filing, and in any event are not the point of novelty

for the present invention. Moreover, as discussed above, one need not even utilize purified proteins in order to practice the claimed invention. Thus, while facially addressing written description, the *Lilly* decision in no way argues against the patentability of the present invention.

Without more, applicants respectfully submit that the examiner has not properly brought into question adequate description of the claimed invention by the instant specification. Thus, it is again submitted that the requirements of §112, first paragraph are satisfied. Reconsideration and withdrawal of the rejection is therefore requested.

## V. Rejections Under 35 U.S.C. §102

### A. *Urban et al.*

Claims 1, 7-10, 18-20, 32 and 33 stand rejected as anticipated under §102(b) by WO 94/04171 to Urban *et al.* The examiner makes only a general allegation that the disclosed composition “appears to be identical or so similar that [it] is indistinguishable” from that which is now claimed. Applicant traverses.

First, despite the PTO’s lack of scientific facilities, the examiner is compelled to make out a *prima facie* of anticipation. Here, the examiner has only pointed to the abstract and claims 1-15 and made no further analysis. It must be pointed out that the abstract and claims merely recite a purified protein that ***binds*** to MHC Class II allotype, and thus is does not even represent an allotype itself. Moreover, as explained above, the present invention requires presence of four distinct allotypes in a single composition. This is nowhere described in the ‘171 application. Thus, the rejection is fatally defective.

Reconsideration and withdrawal of the rejection is therefore requested.

**B. Stott et al.**

Claims 1, 7-10, and 20 stand rejected as anticipated under §102(b) by WO 93/14126 to Stott *et al.* The examiner makes only a general allegation that the disclosed composition “appears to be identical or so similar that [it] is indistinguishable” from that which is now claimed. Applicant traverses.

First, despite the PTO’s lack of scientific facilities, the examiner is compelled to make out a *prima facie* of anticipation. Here, the examiner has only pointed to the abstract and claims 1-8 and made no further analysis. It must be pointed out that the claims merely recite an MHC antigen. As explained above, the present invention requires presence of **four** distinct allotypes in a single composition, whereas the ‘126 application describes only a single antigen. Thus, the rejection is fatally defective.

Reconsideration and withdrawal of the rejection is therefore requested.

**C. Irie et al**

Claims 1, 7-10, and 20 stand rejected as anticipated under §102(b) by U.S. Patent 4,557,931 to Irie *et al.* The examiner makes only a general allegation that the disclosed composition “appears to be identical or so similar that [it] is indistinguishable” from that which is now claimed. Applicant traverses.

First, despite the PTO’s lack of scientific facilities, the examiner is compelled to make out a *prima facie* of anticipation. Here, the examiner has only pointed to claims 1-4 and made no further analysis. It must be pointed out that the claims merely recite an antigenic conjugate of GM2 oligosaccharides and a protein carrier – GM2 is not an MHC antigen. Moreover, as explained above, the present invention requires presence of four distinct allotypes in a single

composition. This is nowhere described in the '931 patent. Thus, the rejection is fatally defective.

Reconsideration and withdrawal of the rejection is therefore requested.

***D. Pietropaolo et al.***

Claims 1, 7-10, and 20 stand rejected as anticipated under §102(e) by U.S. Patent 5,891,437 to Pietropaolo *et al.* The examiner makes only a general allegation that the disclosed composition “appears to be identical or so similar that [it] is indistinguishable” from that which is now claimed. Applicant traverses.

First, despite the PTO’s lack of scientific facilities, the examiner is compelled to make out a *prima facie* of anticipation. Here, the examiner has only pointed to claims 1-16 and made no further analysis. It must be pointed out that the claims merely recite a PM-1 protein or epitope thereof – PM-1 is not an MHC antigen. Moreover, as explained above, the present invention requires presence of four distinct allotypes in a single composition. This is nowhere described in the '437 patent. Thus, the rejection is fatally defective.

Reconsideration and withdrawal of the rejection is therefore requested.

***E. Ravindranath et al.***

Claims 1, 7-10, 18-20, 32 and 33 stand rejected as anticipated under §102(e) by U.S. Patent 6,218,166 to Ravindranath *et al.* The examiner makes only a general allegation that the disclosed composition “appears to be identical or so similar that [it] is indistinguishable” from that which is now claimed. Applicant traverses.

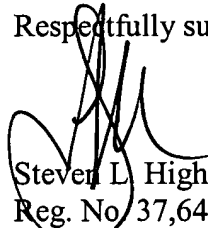
First, despite the PTO's lack of scientific facilities, the examiner is compelled to make out a *prima facie* of anticipation. Here, the examiner has only pointed to the abstract and claims 1-30 and made no further analysis. It must be pointed out that other than claim 19, the compositions described are drawn to a single cell. As explained above, a single cell cannot have four allotypes, it can only have one. And with regard to claim 19, there is nothing in the '166 patent to suggest combining multiple cells (at least four) each with different allotypes. Thus, the rejection is fatally defective.

Reconsideration and withdrawal of the rejection is therefore requested.

**VI. Conclusion**

Applicants respectfully request entry of the amendments and examination of the claims as set forth in §I, above. Should the examiner have any questions regarding this submission, a telephone call to the undersigned is invited.

Respectfully submitted,



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